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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,764	03/25/2004	Thomas C. May	MIT5038USNP	5892

27777 7590 05/28/2010  
PHILIP S. JOHNSON  
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NEW BRUNSWICK, NJ 08933-7003

EXAMINER
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BATES, DAVID W

ART UNIT	PAPER NUMBER
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3775

NOTIFICATION DATE	DELIVERY MODE
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05/28/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jnjuspatent@corus.jnj.com  
lhowd@its.jnj.com  
gsanche@its.jnj.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/808,764	<b>Applicant(s)</b> MAY ET AL.	
	<b>Examiner</b> DAVID W. BATES	<b>Art Unit</b> 3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,3,5,7 and 9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,5,7 and 9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

In view of the appeal brief filed on March 3, 2010, PROSECUTION IS HEREBY REOPENED.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below

### ***Claim Objections***

1. Claim1 is objected to because of the following informalities: The word “though” in line 6 of the claim needs to be changed to “through”. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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3. Claims 1, 3, 5, 7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Singhatat (US 2004/0133239 A1) in view of Wahl et al. (US 6,228,086 B1).

4. Regarding claims 1, 7 and 9, Singhatat teaches:

**An implantable cross-pin** (a pin shaped device {suture anchor 400; fig. 7}, capable of use as a cross-pin, see below) **comprising:**

**an elongated member** (anchor 400) **having a proximal end** (440), **a distal end** (end oriented down in fig. 7, above the nose portion {distal end 450}; see marked up figure), **and an outer surface;**

**a nose member** (distal end 450, ribbed section beyond the bottom of the proximal end) **extending out from the distal end of said elongated member having a proximal end and a distal end** (see marked up figure);

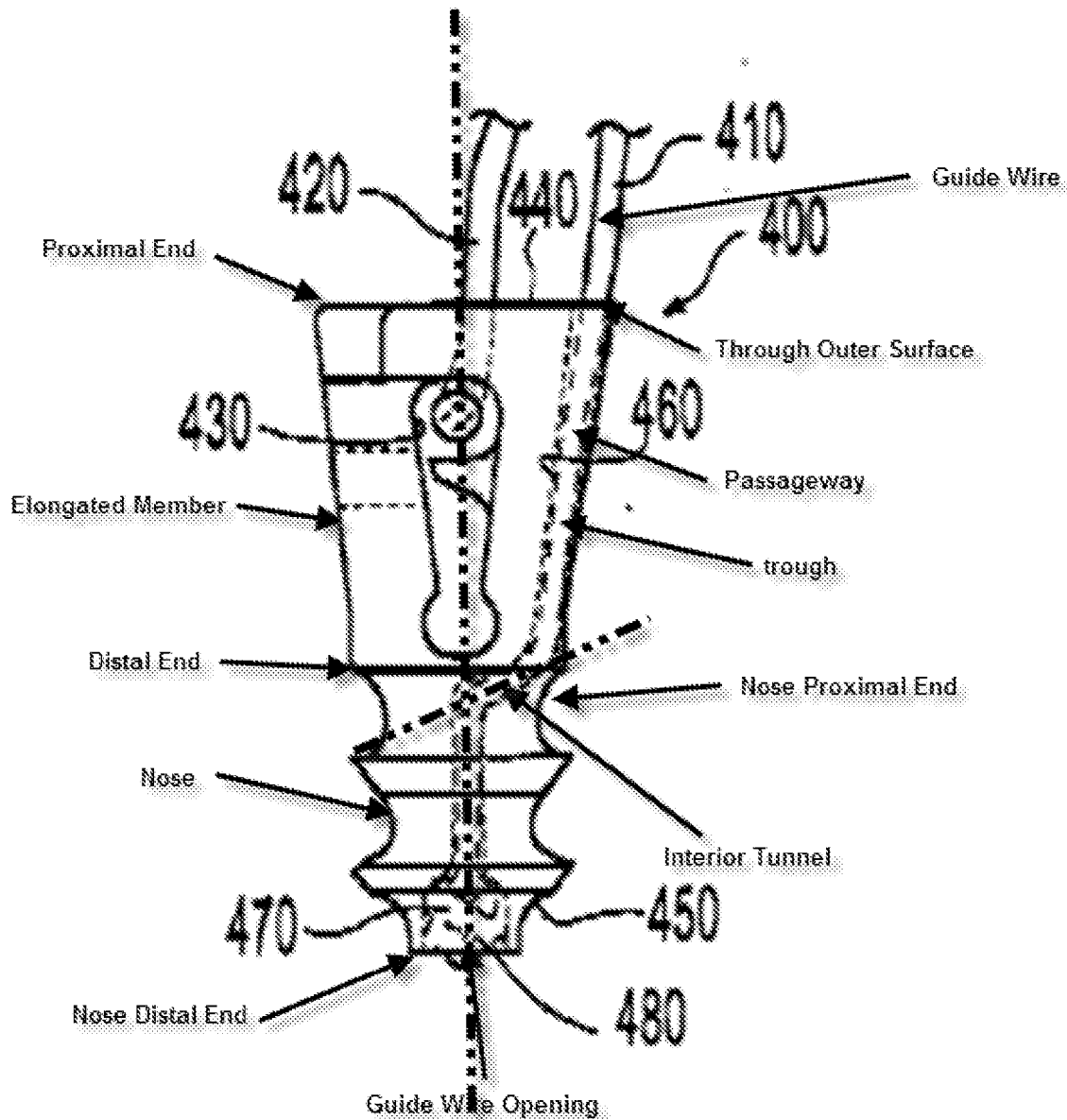
**an axial trough in the elongated member extending through the outer surface,**  
**a guide wire opening in the distal end** (at recess 480 and the first centrally aligned portion which attaches to the tunnel {oblique portion}) **of the nose member and concentric with the central longitudinal axis of the elongated member** (see marked up figure);

**an interior tunnel** (the oblique portion; see marked up figure) **having a passage with an enclosed circular perimeter in the nose member extending from the guide wire opening** (the portion concentric with the body) **and extending into the trough** (the portion 460) **such that the passage is in communication with the guide wire opening and the trough, the interior tunnel being obliquely oriented relative to the**

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**central longitudinal axis of the elongated member; and**  
**a guide wire (suture portion 410) seated in the axial trough and extending through**  
**the interior tunnel and the guide wire opening;**  
**wherein the cross-pin comprises a biocompatible material [0040].**

A pin is defined as “a small, slender, often pointed piece of wood, metal, etc., used to fasten, support, or attach things” (Random House Dictionary, 2010). Both the suture anchor 400 of Singhatat and the nail 1 of Wahl et al. read upon this definition.



*Fig. 7*

Singhatat does not teach:

- The device to be for use in an ACL repair procedure; nor

- **The said trough having a proximal end, a distal end, a bottom, opposed ends, an open top, and a passageway.**

There is no reason that either the Singhatat device or the Wahl et al. device could not be used in an ACL repair procedure, and in fact, could not be used as a cross-pin. Were either of the devices threaded down a guide wire and driven into a drilled opening in the femur in which the tendon is prepared as shown in fig. 4 of the instant application, the device would cause identical fixation of the ACL graft, as produced by the instant invention (described in [0019] of instant application).

It is unclear as to the purpose and criticality of the open trough design. The design appears to be merely design choice. Applicant's disclosure has shown advantages in his design to be that 1) the invention has reduced the need for multiple length implants [0003], 2) the implant can be revised/removed during the surgery [0003], and 3) the implant provides uni-cortical (single bone) fixation of a tendon. It is unclear how an open trough is required to allow any of these goals to be achieved.

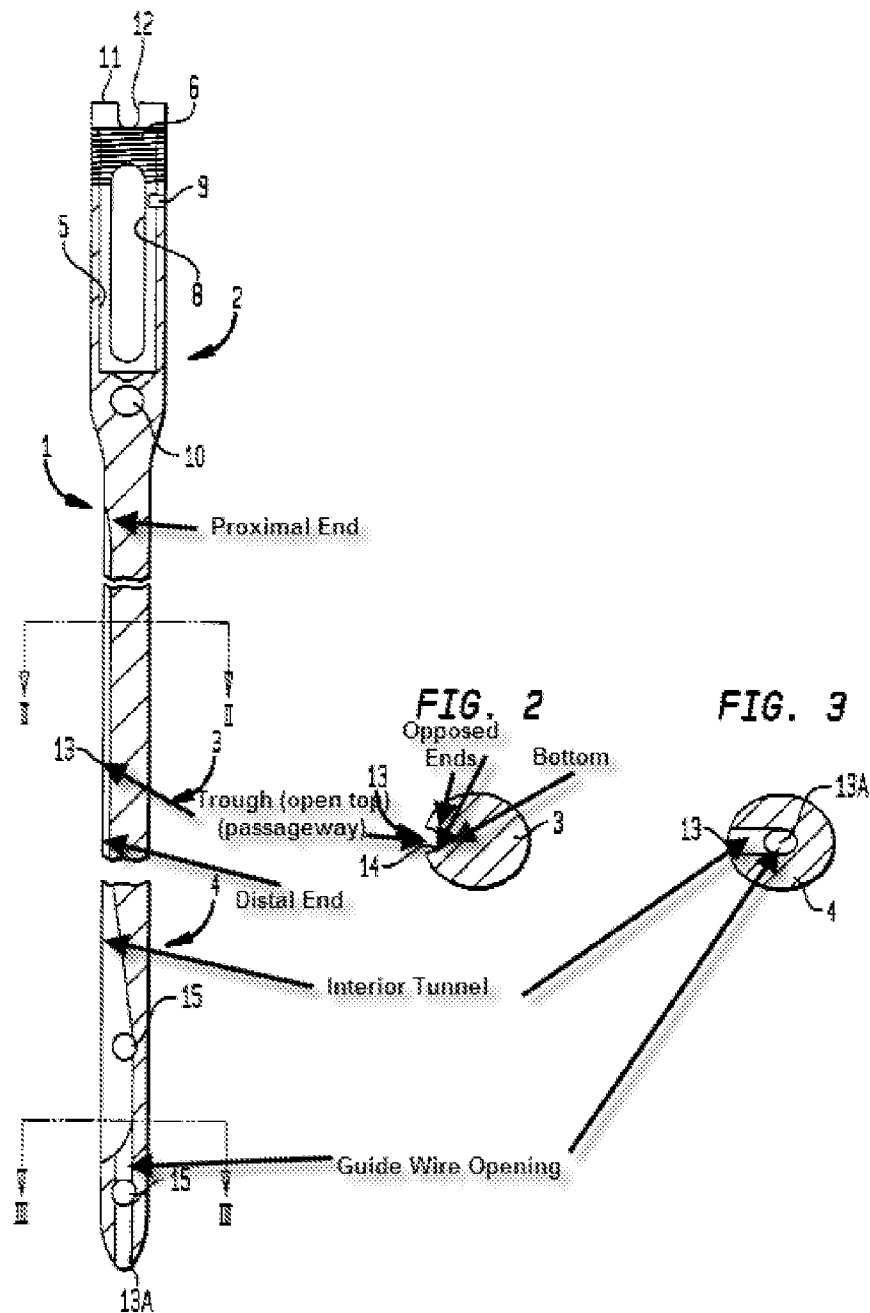
Wahl et al. teach an intramedullary nail having a wire groove 13 having a trough portion (best seen at figs. 1 and 2), and a tunnel (wire channel 13A) in the nose region. The tunnel has a portion which is oblique to the longitudinal axis of the device, and connects the trough 13 and guide wire opening 13A. (See marked up figure).

It would have been obvious to one with ordinary skill in the art at the time of the invention to substitute the trough design for the enclosed portion 460 of Singhatat since doing so would have predictably achieved the result of providing an insert which need

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not be cannulated (for the entire length), and therefore has a smaller cross section to reduce risk of fat embolism (col. 3, lines 16-23).

5. Regarding claims 3 and 5, Singhatat have taught the use of "any suitable biocompatible material" [0040] including resorbable polymers.





***Response to Arguments***

6. Applicant's arguments, see the brief, filed March 8, 2010, with respect to the rejection of claims 1, 3, 5, 7, and 9 under 35 U.S.C. 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground of rejection is made in view of Singhatat and Wahl et al.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID W. BATES whose telephone number is (571)270-7034. The examiner can normally be reached on Monday-Friday 9:00AM - 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tom Barrett can be reached on 571-272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. W. B./  
Examiner, Art Unit 3775

/Thomas C. Barrett/  
Supervisory Patent Examiner, Art  
Unit 3775